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EXAMINER

HAMA, JOANNE

ART UNIT	PAPER NUMBER
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1632

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Applicant filed a response to the Final Action of January 14, 2008 on June 18, 2008. Claims 1-5, 7, 17 are amended.

Claims 1-25 are under consideration.

Request for Reconsideration:

11. (cont.)

35 USC § 112, 2nd parag.

Applicant's arguments, see page 15 of Applicant's response, filed June 18, 2008, with respect to the rejection of claims 1-5, 7 as being indefinite have been fully considered and are persuasive. Applicant has amended the claims to include the articles, "the" or "a." The rejection of claims 1-5, 7 has been withdrawn.

35 USC § 101

Claims 1-25 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for reasons of record, July 14, 2005, April 4, 2006, May 7, 2007, January 14, 2008.

Applicant's arguments filed June 18, 2008 have been fully considered but they are not persuasive.

Applicant indicates that with regard to the Examiner indicating that the art teaches that Alzheimer's patients exhibit an increase in SOD and glutathione reductase activity and note that despite Examiner's assertion, not supported by reference to evidentiary data, the art also teaches the opposite. Applicant refers

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to publications and indicates that "(f)alling levels of glutathione are associated with disease such as AIDS, respiratory diseases and infection, osteoarthritis, **Alzheimer's** and even aging itself" (Applicant's emphasis, Applicant's response, pages 5-6). In response, the Examiner has supported the issue that Alzheimer's patients exhibit an increase in SOD and glutathione reductase activity (Office Action, January 14, 2008, page 14, references to Delibas et al., 2002 and Lovell et al., 2000). With regard to Applicant referring to journal articles that indicate falling levels of glutathione being associated with disease including Alzheimer's disease, the Examiner cannot comment on the articles as they were not provided. With regard to Applicant indicating that falling levels of glutathione are related to various diseases, indicating that the claimed mice exhibit a decrease in SOD and glutathione reductase activity is not indicative that the mice are models of Alzheimer's disease. As indicated by the art indicated by Applicant, reduced SOD and glutathione reductase activity results in a number of diseases and is not necessarily indicative that the mice are models of Alzheimer's disease. In addition to this issue, as indicated by the Examiner, reduced levels of SOD and glutathione reductase are not necessarily indicative of Alzheimer's disease as Alzheimer's disease patients have been shown to exhibit increased SOD and glutathione reductase (see Delibas et al., 2002 and Lovell et al., 2000).

Applicant indicates that Example 8 teaches that "(t)he deficiency in the mechanisms for protection against free radicals was also revealed in patients suffering from Alzheimer's disease, thus confirming the relevance of this animal model." Applicant requests an affidavit under 37 CFR 1.104(d)(2) that explains

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the Examiner's basis and rational to enable a formal response to this aspect of the rejection (Applicant's response, pages 6-7). In response, it is not entirely clear what Applicant would like the Examiner to address. With regard to 37 CFR

1.104 (d)(2):

When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons.

if Applicant intends to indicate that the Examiner was depending on personal knowledge that If Applicant intends to mean that the Examiner's assertion that the deficiency in the mechanisms for protection against free radicals are not confirmation of Alzheimer's disease, the Examiner has cited the teachings of Delibas et al., 2002 and Lovell et al., 2000.

Applicant indicates that the Office Action has not rebutted with any evidence of substance to the teachings regarding the apoptotic phenotypes exhibited by the transgenic mice described in Applicant's disclosure. Applicant refers to the specification, pages 6-7, wherein the specification teaches that the mice exhibit sensitivity to apoptosis and impairments of the metabolism of calcium and free radicals which are exhibited in Applicant's mouse model. Applicant indicates that the Office Action ignores these teachings with only conclusory statements and without any basis for deeming the teachings in the specification as without merit. Applicant request an affidavit under 37 CFR 1.104(d)(2) (Applicant's response, page 7). In response, as discussed in the

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Office Action, May 7, 2007, page 5, nothing in the art teaches a relationship between apoptotic lymphocytes and Alzheimer's disease. With regard to 37 CFR 1.104 (d)(2), the Examiner was not rejecting the instant claims based on personal knowledge. Rather, the Examiner has performed a search of the art and has not found any teaching between the relationship of apoptotic lymphocytes and Alzheimer's disease such that the claimed animals are a readily usable model. As for the phenotype of free radicals, the art, as discussed above, indicates that decreased levels of SOD and glutathione reductase are not indicative of Alzheimer's disease.

Applicant indicates that the Office Action is clear in the intent to dismiss Applicant's utility and substitute a utility with a rational chosen by the Office, "while the mice described in the specification exhibit apoptotic lymphocytes, it is not clear what disease or disorder apoptotic lymphocytes is a symptom of. As such, the use of the claimed animals as a model of apoptotic lymphocytes is not readily apparent." Applicant has suggested a different utility and supported that utility with the specification and other evidence. It is not proper for the Office to select another utility as the utility upon which to base a rejection. Only one utility is required under 35 USC § 101 (Applicant's response, pages 7-8). In response, while Applicant asserts that the claimed animals are a model of disease and indicates the phenotypes the claimed animals exhibit, the Examiner does not find Applicant's assertion that the claimed animals are a model of disease to be persuasive. Applicant indicates that the claimed animals have apoptotic lymphocytes. However, the art does not teach a relationship

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between mutated PS1, apoptotic lymphocytes, and Alzheimer's disease, such the claimed animals can be used.

Applicant indicates that the specification clearly indicates a specific utility, a utility stated rather than implied. In the sentence bridging pages 5-6, "it corresponds to a practical model which is representative of the phenomena of cell death in AD." This one utility is clearly stated. The Office cannot properly base a rejection based on assignment of some other utility deemed "implied" (Applicant's response, page 8). In response, while Applicant indicates that the claimed animals are a model of cell death in AD (wherein the specification teaches apoptotic lymphocytes, e.g. see page 10, legend of Figure 2), neither the art nor the specification teaches a relationship between mutant PS1, apoptotic lymphocytes, and AD such that the animal is a model of apoptotic lymphocytes seen in Alzheimer's patients. While Applicant asserts a use of the claimed animals as a model of disease, the Examiner finds that the claimed animals lack specific and substantial utility for its asserted use. The claimed animals lack specific utility because the art does not provide guidance that apoptotic lymphocytes is a phenotype characteristic of Alzheimer's patients such that the claimed animals are a model of this aspect of Alzheimer's disease. The claimed animals also lack substantial utility because the art does not teach that apoptotic lymphocytes are a symptom of Alzheimer's disease such that the claimed animals can be used as a model of disease. While Applicant indicates a utility of the claimed animal in the specification, the art at the time of filing does not support an artisan finding the claimed animals as useful because the art does not

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teach a relationship between PS1, apoptotic lymphocytes, and Alzheimer's disease.

With regard to the Office Action indicating that it is unclear what use apoptotic lymphocytes have, Applicant indicates that apoptotic lymphocytes are renewable tissue and the model makes it possible to measure these symptoms in the cells of renewable peripheral tissue (Applicant's emphasis, Applicant's response, page 8-9). In response, while Applicant indicates this use of the apoptotic lymphocytes, this use is not specific and substantial. As discussed above, the art does not teach that apoptotic lymphocytes or renewable tissues are a symptom of Alzheimer's disease such that the cells obtained from the claimed animals can be used as a model of disease.

Applicant indicates that in the paragraph bridging pages 7 and 8 of the Office Action appears to require anticipation to provide utility. The Office Action has set a legal standard that the art has to provide the utility of what is novel. Applicant indicates that utility is clearly supported in the specification for example at page 2, ("(m)utations in these genes have been demonstrated to induce an overproduction of an a-beta especially of the long form alpha-beta42 and to the early appearance of the pathology and symptoms which are similar to those of sporadic forms of AD,") and utility of the present invention is further evidenced by this teaching (Applicant's response, page 9). In response, Applicant's citation of page 2 does not provide an artisan guidance that Alzheimer's patients exhibit apoptotic lymphocytes such that the claimed animals can be used.

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With regard to the Office Action indicating, "...lymphocytes are not models of brain cells. As such, this asserted use is not persuasive," Applicant indicates that the Office is assuming for itself that the Office, not Applicant, determines a utility upon which a rejection can be based. Applicant has not asserted that peripheral tissue cells are models of any particular type of cell. Applicant has disclosed a utility of a lymphocyte as a peripheral tissue that has some characteristics associated with neurodegenerative disease associated with oxidative stress. Evidence tying such stress to AD is uncontroverted (Applicant's response, pages 9-10). In response, while Applicant indicates that lymphocytes has some characteristics associated with neurodegenerative disease associated with oxidative stress, this does not provide guidance for an artisan to use the claimed invention because the art does not provide guidance between the relationship of PS1, apoptotic lymphocytes, and Alzheimer's disease.

With regard to the issue of apoptosis in the brain, Applicants stand by the assertion that Chui shows a relationship between apoptosis at the level of neurons and AD. Applicant indicates that nowhere in the statutes can be found of any code that requires a showing of apoptosis in the brain and the code is not specific to any particular evidence required (Applicant's response, page 10). While Applicant indicates that they stand by the assertion that Chui shows a relationship between apoptosis at the level of neurons and AD, it is unclear what this statement has to do with showing the relationship between apoptotic lymphocytes, PS1, and Alzheimer's disease, such that the claimed animals can be used.

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The Office Action indicates, "it cannot be extrapolated that apoptotic lymphocytes are models of Alzheimer's disease." Applicant indicates that the statement is not fully supported by the simple premise that lymphocytic cells are not models of neuronal cells and requires an affidavit under 37 CFR 1.104(d)(2). In response, the Examiner was not depending on personal knowledge. Rather, the Examiner has looked through the art for guidance on other artisans using lymphocytes as models of neuronal conditions and could not find any art. As such, because there is no guidance for the relationship between PS1, apoptotic lymphocytes, and Alzheimer's disease, the instant invention lacks utility.

Applicant refers to pages 5-7 of the specification that provides guidance that the claimed invention has specific, substantial, and credible utility (Applicant's response, pages 10-11). In response, while the specification asserts the utility of the claimed animals, the Examiner has not found these assertions to be persuasive that the claimed animals have a specific and substantial utility. In searching the art, the art provides no guidance that there is a relationship between PS1, apoptotic lymphocytes, and Alzheimer's disease such that the claimed animals are a model for any disease or disorder.

Applicant indicates that no assertion in the Office Action discredits Eckert et al. Accordingly, the associations of the instant invention to the art teachings are unchallenged and therefore should be deemed credible (Applicant's response, page 11). In response, Applicant appears to be referring to Eckert et al., 1997 and 1998, wherein Eckert et al. teach that the impairments of the metabolism of calcium and of free radicals which are observed in this model are

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similar to the increase in the latent period for the calcium response and oxidative stress which are observed with Alzheimer's patients. With regard to this issue, indicating that the claimed animals are a model of impaired metabolism of calcium and of free radicals is a general utility of the claimed invention because this phenotype (which ultimately leads to apoptosis) is found in a number of medical conditions. While the claimed animals have a general utility in being used to treat apoptosis, this is not a specific use. Again, this is because the art does not teach a relationship between PS1, apoptotic lymphocytes, and any disease or disorder.

Thus, the claims remain rejected.

35 USC 112, 1st parag., Enablement

Claims 1-25 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for reasons of record, July 14, 2005, April 4, 2006, May 7, 2007, January 14, 2008.

Claims 1-25 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention, for reasons of record, July 14, 2005, April 4, 2006, May 7, 2007, January 14, 2008.

Applicant's arguments filed June 18, 2008 have been fully considered but they are not persuasive.

Applicant indicates that a declaration was filed wherein Applicant declared that the statements of the specification were believed to be true. Accordingly, citation to the specification is no mere assertion and must be treated as evidence (Applicant's response, page 12). In response, the Examiner was not indicating that the specification was false. Rather, in light of what was taught by the specification and what was known in the art, Applicant's specification raised the issue of utility and enablement such that an artisan would not know how to use the claimed animals. The Examiner believes that the claimed animals exhibit the phenotypes as disclosed in the specification and that apoptosis is one contributing factor of Alzheimer's disease. However, as discussed above, the Examiner has looked in the art to determine what characteristics comprise Alzheimer's disease. Nothing in the art teaches that apoptotic lymphocytes are a characteristic of Alzheimer's disease. Similarly, with regard to the specification indicating that the claimed animals can be used to measure the symptom of apoptosis in renewable tissue, the art does not teach a relationship between apoptosis in renewable tissues and Alzheimer's disease such that the claimed animals can be used. With regard to indicating that the claimed animals exhibit a decrease in SOD and glutathione reductase activity, a characteristic seen in Alzheimer's patients, the art teaches that Alzheimer's patients have also been

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shown to exhibit an increase in SOD and glutathione reductase activity. With regard to using the claimed animals to studying a decrease in SOD and glutathione reductase activity and its relationship to apoptosis, this is not a specific and substantial use because any transgenic animal that exhibits apoptosis can generally be used to study apoptosis. As such, while Applicant has asserted a utility for the claimed animals, the art indicates that it is not readily apparent to an artisan what relationship the phenotypes exhibited by the claimed animal have, such that the claimed animal can be used. Thus, the use of the claimed animal for studies on a PS1-based disease or disorder is not readily apparent.

Applicant indicates that the beginning of the last paragraph, page 12, of the Office Action, another basis of rejection is based on speculation outside the claimed subject matter. The Office Action indicates that, "(r)ather, to make the wide variety of mammalian species and transgene constructs, such that a particular phenotype is exhibited in undue experimentations." Applicant indicates that the claims are not drawn to a "wide variety". Applicant indicates that claim 21 is included in this rejection and perhaps the articles, "a" and "the" have obviated the rejection. In response, it is reiterated that Applicant has claimed a large variety of non-human mammals. "A transgenic mammalian non-human animal" in claim 1 encompasses a wide genus, including cats, squirrels, cows, whales, and deer. Applicant indicates that claim 21 is included in the rejection and is drawn only to mouse and the rejection should not apply to this claim. In response, this aspect of the rejection does not apply to claim 21. However, claim

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21 remains rejected for other reasons other than the breadth of non-human mammals claimed.

Applicant indicates that with regard to the statement, "(a) search in the art has not indicated that there is a relationship between presenilin, apoptotic lymphocytes, and Alzheimer's disease," Applicant requests clarification why this raises a requirement for undue experimentation (Applicant's response, page 13). In response, as indicated above and in previous Office Actions, because the art indicates that there is no relationship between PS1, apoptotic lymphocytes, and Alzheimer's disease. It would require undue experimentation for an artisan to identify the relationship between these three elements without any guidance from the art or specification.

Applicant indicates that nothing in any claims requires "a wide variety of transgenic non-human animals" and that practicing the invention is achieved by practicing any single claimed embodiment. One is not required to practice every conceivable embodiment within the scope of the claim to be liable for infringement (Applicant's response, page 13). In response, as discussed above, the claims encompass non-human mammals which include cats, squirrels, cows, whales, and deer. With regard to Applicant indicating that one is not required to practice every conceivable embodiment within the scope of the claim to be liable for infringement, the issue at hand is not about infringement. Rather, the rejection was written because the art at the time of filing teaches the unpredictability in making transgenic animals with a predictable phenotype (see Office Actions, July 14, 2005, page 8 and May 7, 2007, pages 14-15, Hammer et al., 1990, Hammer

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et al., 1986, Auerbach, 2004 references). Because the art teaches this unpredictability, an artisan is not enabled to practice the claimed invention of a transgenic non-human mammal that expresses a multimutated form of presenilin and exhibits an apoptotic phenotype in renewable peripheral tissue.

Applicant indicates that *Wands* guidance clearly teaches that undue experimentation relates to practicing an additional or the next embodiment, clearly not a requirement that all must be tested. *Wands* makes it quite clear that the breadth of scope and the possibility or even certainty of inoperative embodiments cannot constitute a proper basis for rejection (Applicant's response, page 13). In response, enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art,

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(7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In applying Wands to the instant invention, the Examiner considered the Wands factors and found that undue experimentation is required with regard to the claimed invention. In addition to the issue discussed above regarding it being undue experimentation for an artisan to determine what the relationship is between PS1, apoptotic lymphocytes, and a disease or disorder such that an artisan can use the claimed animals, the claims also encompass other issues of undue experimentation. This includes the art teaching that making transgenic animals with a predictable phenotype is not routine in the art (Office Actions, July 14, 2005, page 8 and May 7, 2007, pages 14-15, Hammer et al., 1990, Hammer et al., 1986, Auerbach, 2004 references). Applicant's claims encompass a wide variety of transgenic mammalian species and post-filing art indicates that it is not routine making different transgenic species in mammals with predictable phenotypes. It is noted that in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 38 USPQ 189 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. In re Dreshfield, 110 F.2d 235, 45 USPQ

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36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

With regard to Applicant indicating that pages 15 and 16 of the Office Action uses the phrases, "the specification does not teach" and "(n)othing in the specificalton teaches" and Applicant takes this to mean that hard "evidence was not found in the specification." Applicant indicates that the Office Action provides no evidence that renewable tissues from the same germ line that contains the same constitutively active promoter and a gene for multmutated presenilin would not behave as other cells with similar genetic make up. Applicant note that that some renewable tissues clearly will not have an apoptotic phenotype (Applicant's response, page 14). In response, as discussed above, the claims broadly encompass any renewable tissue. However, the specification only teaches lymphocytes. The specification does not provide guidance for an artisan to practice the full breadth of the claimed invention as it is drawn to any renewable tissue. With regard to Applicant indicating that claim 3 is restricted to T lymphocytes and that the claim remains rejected (Applicant's response, page 14), it is noted that this aspect of the rejection does not apply to claim 3. However, claim 3 remains rejected for other reasons other than the breadth renewable tissues.

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Applicant indicates on page 17, the Office Action discounts the evidence in the specification that clearly supports association with Alzheimer's disease and again repeats an unsubstantiated claim that the phenotypes of Example 8 "are not indicative that the mice have any symptoms of Alzheimer's disease." In response, the Examiner addressed this issue on page 14 of the Office Action, January 14, 2008 and referred to publications by Delibas et al., 2002 and Lovell et al., 2000.

With regard to the Office Action on page 17 indicating that "(a)s such, the use of the mice with regard to apoptotic lymphocytes to treat Alzheimer's disease is not readily apparent." Applicant indicates that they have not claimed use of the mice to treat Alzheimer's disease. Applicant requests an affidavit under 37 CFR 1.104 (d)(2) if the rejection is to be maintained. In response, the Examiner was not relying on personal knowledge. As discussed above, the Examiner was relying on the art for guidance on using transgenic animals that overexpress mutant presenilin. The art teaches that presenilin has a role in Alzheimer's disease and that a search in the art has not provided guidance for making presenilin overexpressing animals that have a disease or disorder other than Alzheimer's disease such that the claimed animals can be used. While Applicant indicates that the claimed animals have no claims drawn to their use to treat Alzheimer's disease, neither the art nor the specification provides other uses for the claimed animals. While Applicant indicates that the claimed animals exhibit phenotypes such as reduced levels of SOD and glutathione reductase and apoptotic lymphocytes and indicates that the claimed animals can be used as a

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model for this condition, the use of the animals for this condition is a general use of the claimed animal because there are many other diseases (e.g. arthritis) that have reduced levels of SOD and glutathione reductase and exhibit apoptosis.

Thus, the claims remain rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Joanne Hama/
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